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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,856	04/10/2002	Olaf Weber	Le A 33 771	5595

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Jeffrey M Greenman
Bayer Corporation
400 Morgan Lane
West Haven, CT 06516

EXAMINER	
FOLEY, SHANON A	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,856	WEBER ET AL.	
	Examiner	Art Unit	
	Shanon Foley	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 2* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/13/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: The disclosure does not contain a separate "Brief Description of the Drawings" section.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a recombinant parapoxvirus possessing "targeting properties". It is unclear whether the targeting properties are referring to viral tropism or whether the targeting properties are intended to target an immune response against heterologous pathogens with an exogenous insert. The meaning of the term "targeting properties" is not clearly defined in the specification. Pages 1, 3 and 4 (for example) of the specification discuss parapoxviruses for organ, tissue and/or cell-targeted specificity. This discussion implies that the instant parapoxviruses is intended to possess specific tropism for these matrixes. However, page 2 discusses paraspecific immunity induced by parapoxviruses and page 5, 7 and 10 (for example) discuss immunostimulatory properties that are specifically directed against pathogen sequences that have been introduced into the parapoxvirus. Therefore, "targeting properties" is not clearly defined in the specification.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claim is drawn to a method of treating and preventing a disease by administering an effective amount of a parapoxvirus possessing targeting properties. The nature of the claim is drawn to either of the following: 1) targeting a specific organ, tissue or cell receptor with a recombinant parapoxvirus expressing a heterologous ligand on its surface to treat or prevent any disease, or 2) inducing a targeted immune response by administering a recombinant parapoxvirus to treat or prevent any disease. As discussed above, it is unclear what is intended by "targeting properties" because the specification provides discussions implying both concepts of altered tropism and heterologous immunospecificity against a targeted pathogens. Therefore, the true nature of the intended method cannot be determined. The working example shows recombinant cloning of BHV-1 gD in a parapoxvirus. While the recombinant virus demonstrates a more rapid uptake in transfected cells than the wild-type parapoxvirus, there is no evidence presented in the working example that indicates that gD is expressed on the surface of the parapoxvirus. There is also no evidence that the recombinant virus expressing gD is redirected, i.e. targeted, to any specific cell, tissue or organ. In addition, the claims encompass using active and inactivated viruses. The working example uses active virus, but there is no guidance for making and using

an inactive virus that possesses "targeting properties". While inducing an immune response against pathogens with a parapoxvirus encoding heterologous inserts is known in the art, see claims 1-5 of Robinson et al. (WO 97/37031) for example, specific targeting of a poxvirus expressing heterologous targeting entities on the surface of the virus has not been demonstrated. Boulanger et al. (Journal of General Virology. 2000; 81: 675-687) teach that poxviruses have two distinct morphological forms, IMV and EEV. These different forms have different mechanisms of penetration into host cells, see Vanderplasschen et al. (Journal of General Virology. 1998; 79: 877-887). The instant disclosure does not discuss these different forms or mechanisms of viral entry, or provide guidance for overcoming these factors in order to re-target parapoxvirus. Galmiche et al. (Journal of General Virology. 1997; 78: 3019-3027) show construction of EEV particles expressing a single chain antibody on the surface. Although the recombinant EEV particles of Galmiche et al. bind human adenocarcinoma cells in vitro, Galmiche et al. do not observe preferential infection toward these cells. This teaching indicates other yet-to-be identified factors affecting poxvirus infection. With regard to IMV particles, Dallo et al. (Virology. 1987; 159: 423-32) demonstrate that surface polypeptides are related to infectious properties and that alteration of the surface proteins impairs IMV dissemination. The instant disclosure does not teach how the skilled artisan could overcome the obstacles discussed in the art.

There is also no data or evidence presented in the disclosure that would indicate that any disease would be ameliorated or cured upon administration of the recombinant virus. The vaccine art is also provides no teaching of a recombinant virus that is capable of treating or preventing any disease. The specification also provides no guidance for what an "effective

amount" of administration would be in order to treat or prevent any disease in any animal, plant, or other host in need thereof. For these reasons, it is determined that an undue quantity of experimentation would be required of the skilled artisan to make and use the invention.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a pharmaceutical composition comprising a recombinant parapoxvirus intended to target an immune response against heterologous pathogens with an exogenous insert, does not reasonably provide enablement for targeting a specific organ, tissue or cell receptor with a recombinant parapoxvirus expressing a heterologous ligand on its surface. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

As discussed above, due to the lack of guidance provided in the specification for making and using a parapoxvirus expressing a targeting entity on its surface and the lack of guidance regarding what would be an effective amount of the instant construct, the lack of working examples demonstrating a heterologous ligand on the surface of a recombinant parapoxvirus or specific targeting features, the indeterminate nature of the invention, and obstacles in altering surface proteins of poxviruses as evidenced by the teachings of Boulanger et al., Vanderplasschen et al., Galmiche et al. and Dallo et al., it is determined that an undue quantity of experimentation would be required of the skilled artisan to make and use the invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Robinson et al. *supra*.

As discussed above, the enabling embodiment of claim 2 is drawn to a recombinant parapoxvirus expressing a foreign insert to induce a targeted immune response against a pathogen. Surface proteins of pathogens are targets of immune responses. Therefore, a parapoxvirus expressing a heterologous surface protein of a pathogen would have targeting properties because an immune response is induced against the heterologous surface protein.

Robinson et al. teach parapoxvirus orf expressing heterologous sequences to induce an immune response against the exogenous sequences, see claims 1-5. The exogenous sequences expressed include the HIV envelope protein and herpes simplex virus glycoprotein, see page 6, lines 25-31 to page 7, lines 21-23. Therefore, Robinson et al. anticipate a recombinant parapoxvirus expressing a heterologous insert to induce a targeted immune response against a pathogen.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shanon Foley